

PATENT
Docket No. 225.00010124IN THE UNITED STATES PATENT AND TRADEMARK OFFICERECEIVED
CENTRAL FAX CENTER

Applicant(s): Schmidt et al.) Group Art Unit: 3743
)
Serial No.: 10/695,436) Examiner: Unassigned
Confirmation No.: 4462)
Filed: 28 October 2003)
)
For: CONTROL OF RESPIRATORY OXYGEN DELIVERY

APR - 7 2004

OFFICIAL

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. As this patent application was filed after June 30, 2003, copies of the U.S. patents and U.S. patent application publications listed on the attached 1449 form(s) have not been submitted). Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Also enclosed is a copy of the International Search Report issued in the corresponding international patent application (PCT/US98/15490).

Information Disclosure Statement

Page 2 of 2

Applicant(s): Schmidt et al.
Serial No.: 10/695,436
Confirmation No.: 4462
Filed: 28 October 2003
For: CONTROL OF RESPIRATORY OXYGEN DELIVERY

This application is a continuation of U.S. Patent Application Serial No. 10/370,799, filed 20 February 2003. In accordance with 37 C.F.R. §1.98(d), copies of documents previously cited by or submitted to the U.S. Patent and Trademark Office in connection with Applicants' prior application(s) listed above, are not included herewith.

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

Respectfully submitted for

Schmidt et al.

By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612)305-1220
Facsimile: (612)305-1228
Customer Number 26813

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 7th day of April, 2004, at 4:00 pm (Central Time).

Jacquelyn K. Torborg
JACQUELYN K. TORBORG

7 APRIL 2004

Date

By:

KW

Kevin W. Raasch
Reg. No. 35,651
Direct Dial (612)305-1218

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 225.00010220	FOR FURTHER ACTION <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</small>	
International application No. PCT/US 98/ 15490	International filing date (day/month/year) 24/07/1998	(Earliest) Priority Date (day/month/year) 25/07/1997
Applicant MINNESOTA INNOVATIVE TECHNOLOGIES & INS. ... et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of **5** sheets.
 It is also accompanied by a copy of each prior art document cited in this report.

1. Certain claims were found unsearchable (see Box I).
2. Unity of Invention is lacking (see Box II).
3. The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
 - filed with the international application,
 - furnished by the applicant separately from the international application,
 - but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - Transcribed by this Authority
4. With regard to the title, the text is approved as submitted by the applicant.
 the text has been established by this Authority to read as follows:
CONTROL DEVICE FOR SUPPLYING SUPPLEMENTAL RESPIRATORY OXYGEN.

5. With regard to the abstract,
 - the text is approved as submitted by the applicant.
 - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:

Figure No. 1 as suggested by the applicant.
 because the applicant failed to suggest a figure.
 because this figure better characterizes the invention.

None of the figures.

2-16-99 D ✓

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/15490

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 1-12, 13-14, 15-28, 29-32, 36
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy.
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims: 33-35
Method of sensing variations in respiration of a patient.
2. Claims: 37-44, 45-51, 52, 59
System for controlling supplemental oxygen delivery.

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/15490

Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

The abstract has been changed as follows:

- Line 3: after "sensor" insert (14)
- Line 4: after "oxygen" insert (20)
- Line 5: after "valve" insert (26)
- after "oxygen" insert (20)
- Line 6: after "controller" insert (10)
- after "valve" insert (26)
- after "controller" insert (10)
- Line 7: after "valve" insert (26)
- Line 8: after "sensor" insert (14)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/15490

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 606 687 A (PURITAN BENNETT CORP) 20 July 1994 see abstract; figures 1-3	33-35
Y	see column 3, line 21 - column 6, line 5 ---	40-42, 47-49, 52-58
X	US 4 648 395 A (SATO TORU ET AL) 10 March 1987 see abstract; figures see column 6, line 42 - line 55 see column 9, line 1 - column 10, line 12 see column 11, line 26 - line 34 see column 12, line 11 - line 23 ---	33-35
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "Z" document member of the same patent family

Date of the actual completion of the international search:

21 December 1998

Date of mailing of the international search report

06.01.99

Name and mailing address of the ISA
European Patent Office, P.B. 5018 Patentbaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl
Fax: (+31-70) 340-3016

Authorized officer

Zeinstra, H

INTERNATIONAL SEARCH REPORT

Int'l. Application No
PCT/US 98/15490

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 099 283 A (FRANCE PROD OXYGENES CO) 25 January 1984 see abstract; figure 1 see page 2, line 36 - page 4, line 18 ---	33-35
X	DE 43 09 923 A (BOESCH WILHELM ;WUEREMBERGER GEBHARD DR (DE)) 29 September 1994 see abstract; figures	37-39, 43-46,50
Y	see column 5, line 42 - column 7, line 12 -----	40-42, 47-49, 52-58

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/15490

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
EP 0606687	A 20-07-1994	US 5438980 A			08-08-1995
		AU 669237 B			30-05-1996
		AU 5262893 A			21-07-1994
		AU 697929 B			22-10-1998
		AU 6420096 A			31-10-1996
		CA 2112884 A			13-07-1994
		DE 606687 T			14-06-1995
		JP 7047126 A			21-02-1995
		US 5630411 A			20-05-1997
US 4648395	A 10-03-1987	JP 1448149 C			11-07-1988
		JP 59008972 A			18-01-1984
		JP 62054023 B			12-11-1987
EP 0099283	A 25-01-1984	FR 2530148 A			20-01-1984
		AT 21628 T			15-09-1986
		CA 1197302 A			26-11-1985
		JP 59077864 A			04-05-1984
		JP 63049512 B			04-10-1988
		US 4567888 A			04-02-1986
DE 4309923	A 29-09-1994	NONE			

INFORMATION DISCLOSURE STATEMENT	Atty. Docket No.: 225.00010124	Serial No.: 10/695,436
	Applicant(s): Schmidt et al.	Confirmation No.: 4462
	Application Filing Date: 28 October 2003	Group: 3743
	Information Disclosure Statement mailed:	7 April 2004

U.S. PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		2,414,747	01/21/47	Kirschbaum			
		2,912,979	11/17/59	Lieber			
		3,400,712	09/10/68	Finan			
		3,400,713	09/10/68	Finan			
		3,493,703	02/03/70	Finan			
		3,734,091	05/22/73	Taplin			
		3,834,383	09/10/74	Weigl et al.			
		4,054,133	10/18/77	Myers			
		4,278,110	07/14/81	Price et al.			
		4,326,513	04/27/82	Schulz et al.			
		4,336,590	6/22/82	Jacq et al.			
		4,381,002	04/26/83	Mon			
		4,457,303	07/03/84	Durkan			
		4,461,293	07/24/84	Chen			
		4,462,398	07/31/84	Durkan et al.			
		4,484,578	11/27/84	Durkan			
		4,506,666	03/26/85	Durkan			
		4,519,387	05/28/85	Durkan et al.			
		4,567,888	02/04/86	Robert et al.			
		4,575,042	03/11/86	Grimland et al.			
		4,584,996	04/29/86	Blum			
		4,612,928	09/23/86	Ticp et al.			
		4,648,395	03/10/87	Sato et al.			

EXAMINER	Date Considered

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		4,665,911	05/19/87	Williams et al.			
		4,681,099	07/21/87	Sato et al.			
		4,686,974	08/18/87	Sato et al.			
		4,686,975	08/18/87	Naimon et al.			
		4,705,034	11/10/87	Perkins			
		4,706,664	11/17/87	Snook et al.			
		4,744,356	05/17/88	Greenwood			
		4,745,925	05/24/88	Dietz			
		4,784,130	11/15/88	Kenyon et al.			
		4,823,788	04/25/89	Smith et al.			
		4,827,922	05/09/89	Champain et al.			
		4,873,971	10/17/89	Perkins			
		4,889,116	12/26/89	Taube			
		4,932,402	06/12/90	Snook et al.			
		4,971,049	11/20/90	Rotariu et al.			
		4,972,842	11/27/90	Korten et al.			
		5,005,570	04/09/91	Perkins			
		5,024,219	06/18/91	Dietz			
		5,038,770	08/13/91	Perkins			
		5,038,771	08/13/91	Dietz			
		5,048,515	09/17/91	Sanso			
		5,052,400	10/01/91	Dietz			
		5,074,299	12/24/91	Dietz			
		5,099,837	03/31/92	Russel, Sr. et al.			

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Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		5,103,814	04/14/92	Maher			
		5,137,017	08/11/92	Salter			
		5,165,397	11/24/92	Arp			
		5,251,632	10/12/93	Delpy			
		5,280,780	01/25/94	Abel			
		5,282,464	02/01/94	Brain			
		5,315,990	05/31/94	Mondry			
		5,323,776	06/28/94	Blakeley et al.			
		5,360,000	11/01/94	Carter			
		5,365,922	11/22/94	Raemer			
		5,388,575	02/14/95	Taube			
		5,398,676	03/21/95	Press et al.			
		5,398,682	03/21/95	Lynn			
		5,429,123	07/04/95	Shaffer et al.			
		5,443,062	08/22/95	Hayes			
		5,490,502	02/13/96	Rapoport et al.			
		5,495,848	03/05/1996	Aylsworth et al.			
		5,546,933	08/20/96	Rapoport et al.			
		5,558,086	09/26/96	Smith et al.			
		5,582,164	12/10/96	Sanders			
		5,603,315	02/18/97	Sasso, Jr.			
		5,626,131	05/06/97	Chua et al.			
		5,664,562	09/09/97	Bourdon			
		5,692,497	12/02/97	Schnitzer et al.			

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		5,697,364	12/16/97	Chua et al.			
		5,735,268	04/07/98	Chua et al.			
		5,752,509	05/19/98	Lachmann et al.			
		5,803,066	09/08/98	Rapaport et al.			
		5,810,759	09/22/98	Merz			
		5,813,399	09/29/98	Isaza et al.			
		5,848,591	12/15/98	Weismann			
		5,865,174	02/02/99	Kloepel			
		5,915,381	06/29/99	Nord			
		5,925,831	07/20/99	Storsved			
		5,927,274	07/27/99	Servidio et al.			
		5,931,162	08/03/99	Christian			
		5,934,277	08/10/99	Mortz			
		5,937,853	08/17/99	Ström			
		5,954,050	09/21/99	Christopher			
		6,099,481	08/08/00	Daniels et al.			
		6,142,149	11/07/00	Steen			
		6,152,134	11/28/00	Webber et al.			
		6,186,142	02/13/01	Schmidt et al.			
		6,192,883	02/27/01	Miller, Jr.			
		6,220,244	04/24/01	McLaughlin			
		6,371,114	04/16/02	Schmidt et al.			
		6,470,885	10/29/02	Blue et al.			
		6,532,958	03/13/03	Buan et al.			

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		6,561,187	03/13/03	Schmidt et al.			
		20020185126 A1	12/12/02	Krebs			
		20030145852A1	08/07/03	Schmidt et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
		EP 0 099 283 A1	06/13/83	Europe				
		EP 0 606 687 A2	12/27/93	Europe				
		EP 0 753 320 A1	01/15/97	Europe				
		DE 4309923 A1	09/29/94	Germany				
		WO 98/31282 A1 (related to US20020185126 A1)	07/23/98	PCT				X
		WO 99/04841	02/04/99	PCT				

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
		Auerbach, D. et al., "An New Oxygen Canola System Using Intermittent-Demand Nasal Flow", <i>Chest</i> , 74, pp. 39-43 (1978).
		Azhar, N., et al., "Automatic Feedback Control of Oxygen Therapy Using Pulse Oximetry", <i>Annual International Conference of the IEEE Engineering in Medicine and biology Society</i> , 13 pp. 1614-1615 (1991).
		Beddis, et al., "New Technique for Servo-Control of Arterial Oxygen Tension in Preterm Infants", <i>Archives of Disease in Childhood</i> , 54, pp. 278-280 (1979).
		Bhutani, V.K. et al., "Adaptive Control of Inspired Oxygen Delivery to the Neonate", <i>Pediatric Pulmonology</i> , 14, pp. 110-117 (1992).
		Braun, S.R., et al., "Comparison of Six Oxygen Delivery Systems for COPD Patients at Rest and During Exercise", <i>Chest</i> , 102, pp. 694-698 (1992).

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Examiner Initial	Copy Enclosed	Document Description
		Celli, B., et al., "Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease", <i>America J. Respir and Crit Care Medicine</i> , 152, pp. 77-120 (1995).
		Collins, P., et al., "Apparatus for the Servocontrol of Arterial Oxygen Tension in Preterm Infants", <i>Med., & Biol. Eng. & Comput.</i> , 17, pp. 449-453 (1979).
		"Continuous of Nocturnal Oxygen Therapy in Hypoxemic Chronic Obstructive Lung Disease", <i>Annals of Internal Medicine</i> , 93, pp. 391-398 (1980).
		Cotes, J.E., "Continuous Versus Intermittent Administration of Oxygen During Exercise to Patients with Chronic Lung Disease", <i>The Lancet</i> , pp. 1075-1077 (1963).
		Decker, M.J. et al., "Extended Monitoring of Oxygen Saturation in Chronic Lung Disease", <i>Chest</i> , 102, pp. 1075-1079 (1992).
		Make, B., "Oxygen Therapy", Jewish Center for Immunology And Respiratory Medicine, <i>Medical/Scientific Update</i> , 11, (1993).
		Mecikalski, M., et al. "A Demand Valve Conserves Oxygen in Subjects with Chronic Obstructive Pulmonary Disease," <i>Chest</i> , 86, pp. 667-670 (1984).
		Morozoff, P.E., et al. "Automatic Control of Blood Oxygen Saturation in Premature Infants", <i>Second IEEE Conference on Control Applications</i> , pp. 415-419 (1993).
		Morozoff, P.E. et al., "Closed-loop Control of SaO ₂ in the Neonate", <i>Biomedical Instrumentation and Technology</i> , 26, pp. 117-123 (1992)."
		Moyle, J.T.B., "Pulse Oximetry" (BMJ Publishing Group, London), pp. vii, ix, 1-134 (1994).
		Raeemer et al., D.B. "F _I x Controller: An Instrument to Automatically Adjust Inspired Oxygen Fraction Using Feedback Control From a Pulse Oximeter", <i>Journal of Clinical Monitoring</i> , 13, pp. 91-101 (1997).
		Ritchie, G., et al. "Closed-Loop Control of Oxygen Delivery During Aeromedical Evacuation of Patient", <i>Proceeding of the IEEE Southeast Conference</i> , pp. 763-767 (1992).

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Examiner Initial	Copy Enclosed	Document Description
		Sano, A. et al., "Adaptive Control of Arterial Oxygen Pressure of Newborn Infants Under Incubator Oxygen Treatments, <i>IEEE Proceedings</i> , 132, pp. 205-211 (1985).
		Sliwinski, P. et al., "The adequacy of oxygenation of oxygenation in COPD patients undergoing long-term oxygen therapy assessed by pulse oximetry at home", <i>European Respiratory Journal</i> , 7, pp. 274-278 (1994).
		Smith, R., "Carrying On: Portable Oxygen stands out as a value-added service to referral sources", <i>Home Health Care Dealer/Supplier</i> , pp. 43-44, 46 (1997).
		Tehrani et al. "An Automatic Control System for Oxygen Therapy of Newborn Infants", <i>Annual International Conference of the IEEE Engineering in Medicine and Biology Society</i> , 13, pp. 2180-2182 (1991).
		Tehrani et al. "A Feedback Controller for Supplemental Oxygen Treatment of Newborn Infants: A Simulation Study", <i>Med. Eng. Phys.</i> , 16, pp. 329-333 (1994).
		Tiep, B.L. et al., "Low-concentration Oxygen Therapy Via a Demand Oxygen Delivery System", <i>Chest</i> , 87, pp. 636-638 (1985).
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EXAMINER	Date Considered
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	